

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

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|---|--|--|------------------|
| Applicant's or agent's file reference PCG-9009WO | FOR FURTHER ACTION | | See item 4 below |
| International application No. PCT/JP2005/013103 | International filing date (<i>day/month/year</i>) 08 July 2005 (08.07.2005) | Priority date (<i>day/month/year</i>) 09 July 2004 (09.07.2004) | |
| International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/SA/237 | | | |
| Applicant CHUGAI SEIYAKU KABUSHIKI KAISHA | | | |

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
- In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | |
|---|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report |
| <input type="checkbox"/> Box No. II | Priority |
| <input type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI | Certain documents cited |
| <input type="checkbox"/> Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.2).

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|---|---|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70 | Date of issuance of this report 09 January 2007 (09.01.2007) |
| | Authorized officer Yoshiko Kuwahara e-mail: pt07@wipo.int |

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

TRANSLATION

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

Applicant's or agent's file reference

PCG-9009WO

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/JP2005/013103

International filing date (day/month/year)

08.07.2005

Priority date (day/month/year)

09.07.2004

International Patent Classification (IPC) or both national classification and IPC

Applicant

CHUGAI SEIYAKU KABUSHIKI KAISHA

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/Z20 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/Z20.

3. For further details, see notes to Form PCT/ISA/Z20.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language: _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☒ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☒ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☒ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

| Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | | |
|--|--|-------------------|-----|
| 1. Statement | | | |
| Novelty (N) | Claims | 4-6, 19-20, 24-32 | YES |
| | Claims | 1-3, 7-18, 21-23 | NO |
| Inventive step (IS) | Claims | | YES |
| | Claims | 1-32 | NO |
| Industrial applicability (IA) | Claims | 1-32 | YES |
| | Claims | | NO |
| 2. Citations and explanations: | | | |
| <p>Document 1: WO 2004/022739 A1 (Chugai Pharmaceutical Co., Ltd.) 18 March 2004 Document 2: WO 2004/023145 A1 (Kabushiki Kaisha Perseus Protomics) 18 March 2004 Document 3: WO 2004/038420 A1 (Kabushiki Kaisha Perseus Protomics) 06 May 2004</p> <p>The inventions described in claims 1-3, 7-18, and 21-23 do not appear to possess novelty based on documents 1-3 cited in the ISR. Documents 1-3 describe M3B8, M13B3, M6B1, M5B9, and M10D2, which are antibodies binding to glypican 3. The antibodies described in claims 1-3 and 7-18 are found to be those described in documents 1-3.</p> <p>The inventions described in claims 19-20 do not appear to involve an inventive step based on documents 1-3. Documents 1-3 describe M3B8, M13B3, M6B1, M5B9, and M10D2, which are antibodies binding to glypican 3, so cloning DNA encoding these antibodies could be easily achieved by a person skilled in the art.</p> <p>The inventions described in claims 24-27 do not appear to involve an inventive step based on documents 1-3. Producing a large number of peptidic fragments of the C terminal side of glypican 3 and thus obtaining peptide fragments binding to the antibodies in order to specify the epitopes of M3B8 and M13B, which are antibodies binding to the C terminal side of glypican 3, described in documents 1-3, could be easily achieved by a person skilled in the art.</p> <p>The inventions described in claims 1-32 do not appear to involve an inventive step based on documents 1-3. Using peptide fragment containing epitopes of M3B8 and M13B3, which are antibodies binding to the C terminal side of glypican 3, described in documents 1-3, in an immunogen and thus obtaining monoclonal antibodies binding to the peptide fragment, cloning DNA encoding the monoclonal antibodies, producing humanized antibodies using the DNA, and producing peptide fragments that include this epitope by specifying this monoclonal antibody epitope could be easily achieved by a person skilled in the art.</p> | | | |